K033697

FEB 27 2004

February 13, 2004

Section III – 510(k)
Summary of Safety and Effectiveness

Submitter:

Dental Products of USA, Inc.
1460 NW 107 Ave Suite G
Miami, Florida 33172
Phone : (305) 640-9894
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Contact Person: George Echeverri

Summary Prepared Date: October 2,2003-February 13, 2004

Device Name:

I. *Trade Name – Bellini International*
II. *Common Name – Power LED*
III. *Classification Name – Ultraviolet activator for polymerization, per 21 CFR § 872.6070*

Device for Which Substantial Equivalence is Claimes:

I. *3M ESPE AG, Elipar FreeLight, L.E. Demertron*

Device Description:

The Power LED Cordless Curing Light is a device used for the polymerization of dental materials using visible light. It consists of a cordless LED curing handpiece, a battery pack, a battery charger and a remote handpiece holder. The plastic molded handpiece will contain a detachable rechargeable battery pack, an LED light "engine". A printed circuit board with a digital circuit will be utilized to control four different curing modes. Each mode specifies LED timing and audible beep timing. A segmented display will depict the curing modes. A separate pushbutton will activate the light. The molded plastic battery charger will have a single well for charging the battery pack, and Indictor lights to indicate battery charge status.

Intended Use of the Device:

The intended use of the Power LED is for the polymerization of visible light cured materials.

Substantial Equivalence:

Power LED is substantial equivalence to other legally marketed devices in the United States. As Power LED functions in a manner similar to and is intended for the same use as the Elipar Freelight designed by ESPE AG.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2004

Mr. George Echeverri
Export Sales Director
Dental Products of USA, Incorporated
1460 NW 107 Avenue, Suite G
Miami, Florida 33172

Re: K033697
Trade/Device Name: Power LED
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: February 13, 2004
Received: February 17, 2004

Dear Mr. Echeverri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033697

Device Name: Power LED

Indications for Use:

Intended Use for Power LED:

The intended use of Power LED is to act as a polymerization source using visible light to cure composite resins.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033697